



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 6, 2020

Mr. John Reilly
Manager, Regulatory Affairs
Sterilex
110 Lake Front Drive
Hunt Valley, MD 21030

Subject: PRIA Label Amendment – New Sanitization and Viricidal Claims
Product Name: Sterilex Ultra Step
EPA Registration Number: 63761-10
Application Date: February 18, 2020
Decision Number: 561237

Dear Mr. Reilly:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

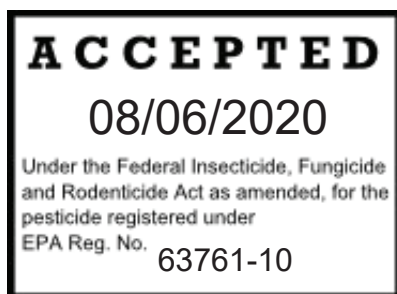
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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at Leavy.Karen@epa.gov.



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure



Sterilex® Ultra Step

Active Ingredients:

N-Alkyl(C₁₄95%,C₁₂3%,C₁₆2%) dimethyl benzyl ammonium chloride..... 1.9%
Sodium Carbonate Peroxyhydrate..... 12.1%

Other Ingredients 86.0%
TOTAL 100.0%

KEEP OUT OF THE REACH OF CHILDREN
DANGER

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

[See [back] [side] [other] [panel] [box] [label] for [additional] [complete] [directions for use] [and] [precautionary statements]]

Manufactured for STERILEX

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Hunt Valley, MD

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Phone (Toll-Free): 1-800-511-1659

Fax: 410-581-8864

Made in USA

EPA Reg. No. 63761-10

EPA Est. No. _____

[NET CONTENTS: _____]

[Item Code: _____]

[LOT NUMBER: _____][BATCH NUMBER: _____] (*NOTE TO REVIEWER – this may be printed on container itself)

[NOT FOR SALE OR USE AFTER: _____] (*NOTE TO REVIEWER – this may be printed on container itself)

[Expiration Date][Exp. Date] [Expiry Date] (*NOTE TO REVIEWER – this may be printed on container itself)

Sterilex Ultra Step is a moisture activated sanitizer and disinfectant specifically designed to improve environmental sanitation on surfaces where conditions favor microorganism growth and cause sanitation concern.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[*]SANITIZING OF HARD, NON-POROUS, INANIMATE, NON-FOOD CONTACT SURFACES

Sterilex Ultra Step eliminates 99.9% of the following bacteria in 5 minutes on hard, non-porous, inanimate, non-food contact surfaces according to the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces:

[*Enterobacter aerogenes* [(ATCC 13048)]]

[*Staphylococcus aureus* [(ATCC 6538)]]

[*Escherichia coli* [(ATCC 11229)]]

[*Listeria monocytogenes* [(ATCC 15313)]]

[*Salmonella enterica* (Salmonella) [(ATCC 10708)]]

[*Salmonella enterica enteritidis* [(ATCC 13076)]]

[*Cronobacter sakazakii* [(ATCC 29004)]]

[*Campylobacter jejuni* [(ATCC 29429)]]

[*Mycoplasma gallisepticum* [ATCC 19610]]

SANITIZING DIRECTIONS FOR NON-FOOD CONTACT SURFACES

Add a solution of 4.9 – 6.1 oz. Sterilex Ultra Step per gallon of water [37 - 46 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution) to sanitize hard, non-porous surfaces. Apply sanitizer use solution to pre-cleaned, hard, non-porous surfaces with a cloth, mop, sponge, sprayer or by immersion. For sprayer applications, use a coarse pump or trigger sprayer. Spray 6-9 inches [15-22 cm] from surface. Do not breathe spray. Treated surfaces must remain wet for 5 minutes, then wipe with sponge, mop or cloth or allow to air dry. Use within 8 hours after powder has been dissolved in water.

[For food processing or other facilities that have installed entryway sanitizing systems.]

ENTRYWAY SANITIZING [SYSTEMS] [FOOTBATHS]

To reduce cross contamination on treated surfaces, apply a solution of 4.9 – 6.1 oz. Sterilex Ultra Step per gallon of water [37 - 46 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution). The entire entryway path must be covered with the [spray] [footbath]. Use within 8 hours after powder has been dissolved in water.

ENTRYWAY [SHOE] [DOORWAY] FOAM DIRECTIONS (Claim not approved in California)

Apply a foam layer that is approximately 0.5 to 2 inches [1.2 cm to 5 cm] thick at all entrances using a foam generating machine or aerator and a solution containing 4.9 – 6.1 oz. Sterilex Ultra Step per gallon of water [37 - 46 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution). Scrape waterproof shoes and boots. Walk through foam. Boots must remain wet for at least 5 minutes prior to entering area. Foamed entranceways must be washed and the foam replaced at least daily or when it (foam/area) appears dirty. Foam should be applied to entrances of buildings, hatcheries, production and packaging rooms to reduce

cross contamination from area to area in the packaging and storage areas of food plants. Use within 8 hours after powder has been dissolved in water.

APPLICATION INSTRUCTIONS FOR USE AS A [FLOOR], [FLOOR MAT], [FOOT PAN] [FLOOR SURFACE] [BOOT] SANITIZER

After cleaning and sanitizing equipment, [apply] [sprinkle] [spread] Sterilex Ultra Step evenly to the [floor] [foot pan] [floor mat] [containment device] [and] [drain] surface, at a minimum rate of 3.7 oz. [105 grams] per 100 square feet of [floor] surface containing no more than 0.97 fl. oz. [28 ml] of moisture per square foot. If moisture amount exceeds 0.97 fl. oz. per square foot, the minimum spread rate of Sterilex Ultra Step must increase to support a minimum concentration of 4.9 oz. Sterilex Ultra Step per gallon of water. Product may be re-applied as needed.

APPLICATION INSTRUCTIONS FOR USE AS A SANITIZER IN A [FLOOR MAT], [FOOT PAN]

[Apply] [Sprinkle] [Spread] Sterilex Ultra Step evenly to the [foot pan] [floor mat] [and] [containment device] [and] [drain] surface, at a minimum rate of 3.7 oz. [105 grams] per 100 square feet of surface containing no more than 0.97 fl. oz. [28 ml] of moisture per square foot. If moisture amount exceeds 0.97 fl. oz. per square foot, the minimum spread rate of Sterilex Ultra Step must increase to support a minimum concentration of 4.9 oz. Sterilex Ultra Step per gallon of water. Ensure complete coverage of the bottom of the [floor mat] [foot pan] [and] [containment device] and re-apply product as necessary.

APPLICATION INSTRUCTIONS FOR USE AS A CLEANER AND DEODORIZER

[Apply] [Sprinkle] [Spread] Sterilex Ultra Step evenly to the [floor] [foot pan] [floor mat] [and] [containment device] [and] [drain] surface, at a minimum rate of 1 oz. [28.4 grams] per square foot of surface. Ensure complete coverage of the bottom of the [floor] [floor mat] [foot pan] [and] [containment device] and re-apply product as necessary.

[]GENERAL DISINFECTION AND CLEANING DIRECTIONS FOR HARD NON-POROUS SURFACES**

Sterilex Ultra Step is a [broad spectrum] [hospital use] disinfectant when applied at a rate of 1.34 – 1.67 lbs Sterilex Ultra Step per gallon of water [160 – 200 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution). Sterilex Ultra Step was tested using the 2013 AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water against:

[*Pseudomonas aeruginosa* [Pseudomonas] [ATCC# 15442]]

[*Staphylococcus aureus* [Staph] [ATCC# 6538]]

[*Salmonella enterica* [Salmonella] [ATCC# 10708]]

APPLICATION INSTRUCTIONS

Remove visible [filth] [soil] from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix 1.34 – 1.67 lbs Sterilex Ultra Step per gallon of water [160 – 200 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution). Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing or spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. In CIP systems, full flow/pressure must be achieved in the system at the start of the contact time and pressure should be maintained for the duration of the contact time. Allow surfaces to remain wet for at least 10 minutes. Do not breathe spray. Rinse all surfaces thoroughly with a potable water rinse. Use within 8 hours after powder has been dissolved in water.

[†] VIRUSES

Sterilex Ultra Step is effective against the following viruses on hard, non-porous surfaces at a rate of 0.92 – 1.15 lbs Sterilex Ultra Step per gallon of water [110 – 138 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution), with a 10 minute contact time in the presence of 400 ppm hard water:

Avian Influenza A [Influenza A (H3N2)] [Strain A/Victoria/3612011]

Feline Calicivirus [Strain F-9]

Norovirus

Rotavirus [Strain Wa (TC Adapted)]

APPLICATION INSTRUCTIONS

Remove visible [filth] [soil] from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix 0.92 – 1.15 lbs Sterilex Ultra Step per gallon of water [110 – 138 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution). Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing or spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. In CIP systems, full flow/pressure must be achieved in the system at the start of the contact time and pressure should be maintained for the duration of the contact time. Allow surfaces to remain wet for at least 10 minutes. Do not breathe spray. Rinse all surfaces thoroughly with a potable water rinse. Use within 8 hours after powder has been dissolved in water.

Sterilex Ultra Step is effective against the following viruses on hard, non-porous surfaces at a rate of 1.69 – 2.12 lbs Sterilex Ultra Step per gallon of water [203 – 254 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution), with a 10 minute contact time in the presence of 400 ppm hard water:

PED Virus [Strain CO 2013]

Porcine Reproductive & Respiratory Syndrome virus (PRRS) [Strain NVSL]

Newcastle Disease virus [Strain Lasota]

Infectious Laryngotracheitis virus [LT virus][Strain LT-IVAX]

APPLICATION INSTRUCTIONS:

Preclean all surfaces by removing visible [filth] [soil] from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix 1.69 – 2.12 lbs Sterilex Ultra Step per gallon of water [203 – 254 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution). Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing or spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. In CIP systems, full flow/pressure must be achieved in the system at the start of the contact time and pressure should be maintained for the duration of the contact time. Allow surfaces to remain wet for at least 10 minutes. Do not breathe spray. Rinse all surfaces thoroughly with a potable water rinse. Use within 8 hours after powder has been dissolved in water.

PRECLEANING OF [WHIRLPOOL BATH], [SPA] AND [JACUZZI TUB SURFACES]

Close the [whirlpool bath], [spa] or [Jacuzzi tub] to bathers. Turn off/close all chemical treatment lines, sensors, chlorine (bromine) feeders and pH chemical adjusters. The amount of water to be treated equals the capacity in gallons of the [whirlpool bath], [spa] or [Jacuzzi tub]. Add 1.67 – 3.34 oz. Sterilex Ultra Step per gallon of water [13 - 25 grams Sterilex Ultra Step per liter of water] to be treated. Briefly start the pump to circulate the solution. Turn off the pump. Wash down the sides, seat of the chair and any and all related equipment with a clean swab, sponge or brush. Drain solution from the unit and rinse cleaned surfaces and equipment with fresh water. Use product within 8 hours after powder has been dissolved in water.

DISINFECTION AND CLEANING OF [WHIRLPOOL BATH], [SPA] AND [JACUZZI TUB SURFACES]

NOTE: During treatment bathers must not enter the [whirlpool bath], [spa] and [Jacuzzi tubs].

Turn off/close all chemical treatment lines, sensors, chlorine (bromine) feeders and pH chemical adjusters. The amount of water to be treated equals the capacity in gallons of the [whirlpool bath], [spa] or [Jacuzzi tub]. Add 1.34 – 1.67 lbs Sterilex Ultra Step per gallon of water [160 – 200 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution) to be treated. Begin circulation of the product to assure even distribution of the product through the piping systems. Circulate the product for at least 10 minutes after the product has been evenly distributed through the piping system. Drain the entire system. Flush (rinse) the entire system by refilling the entire system with clean fresh water. Rinse all cleaned surfaces with fresh water. Use product within 8 hours after powder has been dissolved in water.

PRECAUTIONARY STATEMENTS

Hazard To Humans And Domestic Animals.

DANGER. Corrosive. Causes irreversible eye damage and skin irritation. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear (goggles, face shield, or safety glasses), coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear and waterproof gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal

PESTICIDE STORAGE: Keep out of children's reach. Store in a cool, dry location away from direct sunlight. Keep containers tightly sealed.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

(NOTE TO REVIEWER: The following language is for the nonrefillable pouches having a capacity of 10 pounds or less)

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Completely empty pouch into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the pouch may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty discard packet in trash.

(NOTE TO REVIEWER: The following language is for nonrefillable fiber drum with plastic liner bag containers having a capacity greater than 5 pounds)

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(NOTE TO REVIEWER: The following language is for nonrefillable rigid plastic containers with plastic liner bag containers having a capacity of 10 pounds or less)

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(NOTE TO REVIEWER: The following language is optional for nonrefillable rigid plastic containers having a capacity of 10 pounds or more when “or pressure rinse” appears in the Container Disposal statement)

Nonrefillable container. [Triple rinse] [or] [pressure rinse] container (or equivalent) promptly after emptying. [Pressure rinse as follows: Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Dispose of rinsate as pesticide waste. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.]

[Triple rinse as follows: Fill the container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Dispose of rinsate as pesticide waste. If rinsate cannot be used, follow pesticide disposal instructions. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.]

Optional Marketing Claims

- [BASED OFF OF] [BASED ON] [INCLUDING] [INCLUDES] [USING] [POWERED BY] [PATENTED] [PERQUAT® TECHNOLOGY]
- Sterilex Ultra Step is for use as a non-food contact surface sanitizer, or as a disinfectant, on hard, nonporous surfaces in a variety of premises, including but not limited to, [Federally Inspected Food Processing Facilities], [Federally Inspected Meat And Poultry Plants], [Dairies], [Wineries], [Breweries], [Beverage Manufacturing Facilities], [Dairy Farms], [Swine Farms], [Poultry And Turkey Farms], [Farm Premises], [Hatcheries], [Refrigerated Trucks], [Kennels], [Pet Animal Quarters], [Zoos], [Pet Shops], [Animal Laboratories], [Veterinary Facilities], [Animal Care Facilities], [Food Service Facilities], [Kitchens], [Grocery Stores], [Deli Areas], [Drains]
- Non-Food Contact Surface Sanitizer
- [Floor] [Footpan] [Boot] [Floormat] [Mat] [Drain surface] Sanitizer
- For Use in Non-Food Contact Areas of Dairy, Food, Meat, and Beverage Processing Facilities
- Animal Premise Sanitizer
- Floor sanitizing and deodorizing performance
- [Virucide†] [Virucidal†] [Broad Spectrum] [Hospital use] Disinfectant
- Cleaner
- Patent pending
- No pre-dilution necessary

- Formulated to kill 99.9% of bacteria*
- For use in low moisture or dry processing plants
- For use in low moisture environments
- No need for external drain
- Apply as solid [floor][foot pan][floor mat][boot][drain surface][animal premise] [sanitizer]
- Solid, [floor][foot pan][floor mat][boot][drain surface][animal premise] [sanitizer]
- Effective against Avian Influenza
- Controls and inhibits odor causing bacteria

Optional, Non-Label Marketing Claims

Emerging Viral Pathogen Claims

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

[Sterilex Ultra Step][This product] meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- *Enveloped viruses*
- *Large non-enveloped viruses*
- Sterilex Ultra Step has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, Sterilex Ultra Step can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.
- [Name of illness/outbreak] is caused by [name of emerging virus]. Sterilex Ultra Step kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to [CDC or OIE] website at [pathogen-specific website address] for additional information.

Emerging Viral Pathogen Claim – Terms of Registration

<u>For an emerging viral pathogen that is a/an:</u>	<u>Supporting Virus(es)</u>
Enveloped virus	Feline calicivirus or Rotavirus
Large, non-enveloped virus	Feline calicivirus